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Surgical Wounds Healing By Secondary Intention - 2

Submission date 15/02/2019	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [X] Statistical analysis plan [X] Results [X] Individual participant data
Registration date 25/03/2019	**Overall study status** Completed	
Last Edited 03/07/2025	**Condition category** Surgery	

Plain English summary of protocol

Background and study aims
After an operation, most wounds are closed using stitches or staples. Some wounds cannot be closed in this way and are left open. Sometimes wounds that have been closed may open up again. These “open” wounds are usually left to heal, over time, from the bottom up rather than attempting to close them again by some other means (healing by secondary intention). The most common treatment for these wounds is plain dressings. Another type of treatment is Negative Pressure Wound Therapy (NPWT) which is a relatively new treatment for open surgical wounds. It uses a small machine to apply suction to a wound through a special dressing. Use of NPWT has become more common and is used in around one third of people with open surgical wounds. It is not known which of these (NPWT or wound dressings) is the most effective treatment for surgical wounds healing by secondary intention and which treatment is best value for money. The aim of this study is to compare NPWT to normal wound dressings to see if it makes any difference to how quickly these open wounds heal.

Who can participate?
Patients aged 16 or older with a surgical wound healing by secondary intention

What does the study involve?
Participants receive one of the two treatments (NPWT or wound dressings), selected at random using a computer system. The two groups are compared over 12 months including how long it takes their wounds to heal, number of infections, hospital admissions and further operations, and how much both treatments cost.

What are the possible benefits and risks of participating?
The information from this study may help to treat people with open wounds more effectively in the future. As with any treatment there are always potential risks, although side effects in both treatments are very uncommon. Where negative pressure wound therapy machines are used, the device may present a trip hazard and so care should be taken when moving around. Where a wound is located on the stomach, there is an increased risk of developing a fistula, an abnormal opening between organs and the skin. Where normal wound dressings are used, there may be a

need for frequent dressing changes, sometimes daily. These are usually completed by a nurse. Being in this study will not harm or disadvantage participant's care in any way and participants will be monitored regularly as part of usual NHS care.

Where is the study run from?
University of York (UK)

When is the study starting and how long is it expected to run for?
November 2018 to January 2024

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Catherine Arundel
catherine.arundel@york.ac.uk

Study website
https://www.york.ac.uk/healthsciences/research/trials/ytutrialsandstudies/trials/swhsi-2/

Contact information

Type(s)
Scientific

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Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Sponsor ID: R2319; HTA 17/42/94; 40908

Study information

Scientific Title
A pragmatic, multicentre, randomised controlled trial to assess the clinical and cost effectiveness of negative pressure wound therapy versus usual care for surgical wounds healing by secondary intention (SWHSI 2)

Acronym
SWHSI-2

Study objectives
Negative Pressure Wound Therapy (NPWT) is superior to usual care in the treatment of surgical wounds healing by secondary intention (SWHSI).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/04/2019, Yorkshire and The Humber - Leeds East Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ; +44(0) 207 1048 088; nrescommittee.yorkandhumber-leedseast@nhs.net), ref: 19/YH/0054

Study design
Pragmatic multi-centre randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
Surgical wounds healing by secondary intention

Interventions
Current intervention as of 01/04/2022:
Patients with a potential planned SWHSI (pre-operatively) or a SWHSI occurring at any point following surgery will be screened for potential eligibility by their clinical care team or GP. Patients who agree to take part will receive one of the two treatments selected at random using a computer system.

Intervention: Negative Pressure Wound Therapy (NPWT).
Participants will be treated with negative pressure wound therapy (NPWT). The patients wound is filled with a suitable dressing, and a liner may also be used to protect the wound. A vacuum pump is then attached which applies suction to the wound. A disposable, plastic canister slots into the pump to collect wound exudate and this is removed and replaced either when it becomes full, or at least once a week.
The device is generally used as part of the SWHSI treatment pathway rather than to the point of healing and is administered by both nurses and clinicians.
The use of any CE marked NPWT device, providing pressure of 60-150mmHg, in use within the NHS will be permitted in this trial, given that the principles of any device are similar and there is no evidence to suggest clinical or cost-effectiveness differences between devices. The device will be used in accordance with manufacturer guidance, and the clinical care team, in conjunction with local treatment guidelines, will determine the duration of device use, and whether this includes continuous or intermittent pressure cycles.

Control: Usual Care (no NPWT)
Usual care will be that used locally, without NPWT. This is most likely to be other sorts of wound dressings and use of any dressing type will be permitted. The frequency of dressing changes will continue as per standard practice.

Participants in both groups will be followed up by telephone on a weekly basis until the participant's wound has healed. Following wound healing, a face to face visit will be completed

to assess the wound, complete a wound infection assessment, and to collect a photograph of the healed wound. Healing status will then be confirmed by telephone for two further weeks.

Participants in both groups will be asked to complete short questionnaires at 3 months, 6 months and 12 months which include assessment of pain, wound infection, quality of life and resource use.

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Control: Usual Care (no NPWT)
Usual care will be that used locally, without NPWT. This is most likely to be other sorts of wound dressings and use of any dressing type will be permitted. The frequency of dressing changes will continue as per standard practice.

Participants in both groups will be followed up by telephone on a weekly basis until the participant's wound has healed. Following wound healing, three face to face visits will be completed to assess the wound, complete a wound infection assessment, and to collect photographs of the healed wound.

Participants in both groups will be asked to complete short questionnaires at 3 months, 6 months and 12 months which include assessment of pain, wound infection, quality of life and resource use.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Negative Pressure Wound Therapy; Usual wound dressings

Primary outcome measure

Current primary outcome measure as of 18/11/2020:

Time to healing in days from randomisation (defined using the commonly used and clinically certified criteria 'complete epithelial cover in the absence of a scab (eschar)'). Confirmation of wound healing by a health care professional will initially be participant-reported through weekly telephone contact with the research nurse. Participants will be asked to report if their clinician or nurse has indicated that their wound is healed. In the event the participant reports their wound to be healed, but this has not been confirmed by a healthcare professional, the research nurse will contact the clinical care team to obtain this confirmation. Once wound healing has been confirmed by a healthcare professional and treatment has ceased, participants will undergo clinical assessments on three subsequent consecutive weeks. The first healing visit will be completed face to face wherever possible, during which standardised photographs will be taken of the wound for blinded outcome verification. We will also ask participants to take and return a photograph of the wound themselves. Study-specific instructions will be provided to the participant.
The second and third post healing visits may be completed by telephone if required.

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Secondary outcome measures

Current Secondary outcome measures as of 11/03/2024:
1. Clinical events including antibiotic treatment, hospital admission or discharge, treatment status (including reasons for dressing or treatment failure or change), re-operation (including skin grafting and closure surgery*), amputation and death will be assessed using clinic records and patient-reported events on a weekly basis until the point of wound healing.
*The decision for closure surgery will be made blinded to treatment allocation as far as is possible
2. Wound infection assessed using the Bluebelle Wound Healing Questionnaire (WHQ). The questionnaire includes items to assess signs, symptoms and wound care interventions indicative of surgical site infection (SSI) and can be completed by patient self-report or by healthcare professionals. The tool may be used to assess wounds in hospital or after the patient has been discharged. The WHQ will be completed by the participants themselves at baseline, 3 month follow-up assessments, and will also be completed by the patient at the initial healing visit
3. Wound pain, assessed using a visual analogue scale (with anchors 0 'no pain' and 10 'worst imaginable pain'). The scale will be completed by the participants themselves at baseline, 3, 6 and 12 month follow-up assessments
4. Quality of life, measured using the EQ-5D-5L at baseline, 3 months, 6 months and 12 months follow-up assessments

5. Resource use: wound-related NHS consultations, support (e.g. occupational therapy, in-home adaptions) and out-of-pocket costs collected using a patient-reported questionnaire at baseline, 3, 6 and 12 months

Previous secondary outcome measures as of 01/04/2022:
1. Clinical events including antibiotic treatment, hospital admission or discharge, treatment status (including reasons for dressing or treatment failure or change), re-operation (including skin grafting and closure surgery*), amputation and death will be assessed using clinic records and patient-reported events on a weekly basis until the point of wound healing.
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4. Quality of life, measured using the EQ-5D-5L at baseline, 3 months, 6 months and 12 months follow up assessments
5. Resource use: wound-related NHS consultations, support (e.g. occupational therapy, in home adaptions) and out of pocket costs collected using a patient-reported questionnaire at baseline, 3, 6 and 12 months

Overall study start date
01/11/2018

Completion date

31/01/2024

Eligibility

Key inclusion criteria
1. Aged 16 years or over
2. Has an acute SWHSI (i.e. a wound left open as planned following surgery or a wound initially closed using sutures, clips, or other closure methods and dehisced along the whole or part of its length, and of less than 6 weeks in duration), arising from any surgical specialty and occurring on any part of the body, deemed appropriate to receive either NPWT or wound dressing treatment
3. Has a SWHSI that is considered ready for NPWT treatment (i.e. contains at least 80% viable tissue or has only a very thin layer of slough requiring no further debridement)
4. Patient is not deemed to be malnourished, as per NICE guidelines CG 32 (BMI <18.5 kg/m2; unplanned* weight loss >10% in the last 3-6 months; BMI <20kg/m2 and unplanned* weight loss >5% in the last 3-6 months) or assessed as at high risk of malnutrition using the Malnutrition Universal Screening Tool (MUST)
*Patients with weight loss arising either from underlying comorbidity (e.g. ulcerative colitis) or from the reasons for surgery being completed (e.g. bowel cancer) may be included at the clinician's discretion
5. Willing and able to give informed consent and provide follow-up data

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
696

Total final enrolment
686

Key exclusion criteria
Current participant exclusion criteria as of 01/04/2022:
1. Life expectancy of less than 6 months e.g. undergoing end stage palliative care
2. Active systemic infection (including osteomyelitis) at baseline as defined by clinical and/or laboratory assessment. Note: Patients who have an active infection, but are improving following 1 week's duration of antibiotics may be included at the clinician's discretion
3. Inadequate haemostasis or patients who are at risk of bleeding
4. Chronic wounds non-surgical in origin (e.g. pressure ulcers or foot ulcers)*
*Note diabetic foot ulcers which have been incised and drained or debrided as an inpatient in theatre may be included given this constitutes a surgical wound.
5. Current wound has previously been, or is currently being, treated with NPWT

6. Planned delayed primary closure of the wound
7. Contraindication to NPWT including: presence of unclear undermining in the wound cavity; presence of necrotic tissue, malignant tissue or eschar; wounds involving exposed blood vessels and/or organs, anastomotic sites and/or nerves (including the “open abdomen” where the abdominal fascia is open); wounds situated where, in the opinion of the treating clinician, a vacuum seal cannot be obtained; presence of a non-enteric or unexplored fistula; people requiring emergency airway aspiration, pleural mediastinal or chest tube drainage or surgical suction (removed 07/11/2019: people with a sensitivity or allergy to silver)
8. Currently participating in another wound research study, where the primary outcome time point has not yet been reached

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Date of first enrolment
01/05/2019

Date of final enrolment
13/01/2023

Locations

Countries of recruitment
England

Scotland

United Kingdom

Wales

Study participating centre

Hull University Teaching Hospital NHS Trust
Hull Royal Infirmary
Anlaby Road
Hull
United Kingdom
HU3 2JZ

Study participating centre
University Hospitals of Birmingham NHS Foundation Trust
Queen Elizabeth Medical Centre
Edgbaston
Birmingham
United Kingdom
B15 2TH

Study participating centre
Royal Liverpool and Broadgreen University Hospitals NHS Trust
Royal Liverpool University Hospital
Prescot Street
Liverpool
United Kingdom
L7 8XP

Study participating centre
Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust
Doncaster Royal Infirmary
Armthorpe Road
Doncaster
United Kingdom
DN2 5LT

Study participating centre
The Dudley Group NHS Foundation Trust
Russells Hall Hospital
Pensnett Road
Dudley
United Kingdom
DY1 2HQ

Study participating centre

Royal Cornwall Hospitals NHS Trust
Royal Cornwall Hospital
Treliske
Truro
United Kingdom
TR1 3LJ

Study participating centre
Imperial College Healthcare NHS Trust
St Mary's Hospital
Praed Street
London
United Kingdom
W2 1NY

Study participating centre
The Newcastle Upon Tyne Hospitals NHS Foundation Trust
The Freeman Hospital
High Heaton
Newcastle
United Kingdom
NE7 7DN

Study participating centre
Leeds Teaching Hospitals NHS Trust
St James' University Hospital
Beckett Street
Leeds
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LS9 7TF

Study participating centre
Norfolk and Norwich University Hospitals NHS Foundation Trust
Colney Lane
Norwich
United Kingdom
NR3 7UY

Study participating centre
University Hospitals of Birmingham NHS Foundation Trust
Heartlands Hospital

Bordesley Green East
Birmingham
United Kingdom
B9 5SS

Study participating centre
St George's University Hospitals NHS Foundation Trust
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SW17 0QT

Study participating centre
Mid Yorkshire Hospitals NHS Trust
Pinderfields Hospital
Aberford Road
Wakefield
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WF1 4DG

Study participating centre
Pennine Acute Hospitals NHS Trust
Royal Oldham Hospital
Rochdale Road
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OL1 2JH

Study participating centre
Aneurin Bevan University Health Board
Royal Gwent Hospital
Cardiff Road
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United Kingdom
NP20 2UB

Study participating centre
Queen Elizabeth Hospital Kings Lynn NHS Trust
Gayton Road
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PE30 4ET

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Northumbria Healthcare NHS Foundation Trust
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Nursery Park
Ashington
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NE63 0HP

Study participating centre
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DE22 3NE

Study participating centre
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Kayll Road
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SR4 7TP

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Manchester University NHS Foundation Trust
Manchester Royal Infirmary
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M13 9WL

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Frimley Health NHS Foundation Trust
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51 Little France Crescent
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Southmead Hospital
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BS10 5NB

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Royal Free Hospital
Pond Street
London

United Kingdom
NW3 2QG

Study participating centre
University Hospitals of Leicester NHS Trust
Glenfield Hospital
Groby Road
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United Kingdom
LE3 9QP

Study participating centre
The Shrewsbury and Telford Hospital NHS Trust
Mytton Oak Road
Shrewsbury
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SY3 8XQ

Study participating centre
Worcestershire Acute Hospitals NHS Trust
Worcestershire Royal Hospital
Charles Hastings Way
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United Kingdom
WR5 1DD

Sponsor information

Organisation
Hull University Teaching Hospital NHS Trust

Sponsor details
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Castle Hill Hospital
Cottingham
Hull
England
United Kingdom
HU16 5JQ
+44 (0)1482 461883
research.development@hey.nhs.uk

Sponsor type
Hospital/treatment centre

Website
https://www.hey.nhs.uk/research/contact-research/

ROR
https://ror.org/01b11x021

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Documentation relating to the study will be made available as the study progresses. Results will be published in peer reviewed journals. Summaries of the findings will be sent to NICE and other relevant bodies so that findings can inform clinical practice. The trialists will also work with the relevant National Clinical Director in the Department of Health to ensure findings are considered when implementing policy. The trialists will also work with relevant Speciality Advisory Committees to incorporate findings into training curriculum's for clinicians.

Intention to publish date
30/06/2024

Individual participant data (IPD) sharing plan
Anonymised datasets generated and analysed during the current study will be stored in a publicly available open research repository (https://osf.io/echxv). Data is anticipated to be

available via this repository by end 2024, following completion of analysis and subsequent publication. Sharing of this anonymised data is covered by original participant consent for the SWHSI-2 trial which permits sharing of data to support future research via sharing anonymously.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		25/10/2021	19/01/2023	Yes	No
Other files	Health economics analysis plan version 1.0	14/12/2022	03/02/2023	No	No
Statistical Analysis Plan	version 1.0	14/12/2022	03/02/2023	No	No
HRA research summary			28/06/2023	No	No
Results article		15/04/2025	23/04/2025	Yes	No
Dataset		13/05/2025	21/05/2025	No	No
Results article	outcomes and learning from the internal pilot phase and main trial	02/07/2025	03/07/2025	Yes	No